

Notice of Allowability

Application No.

10/047,135

Examiner

Brian Szmal

Applicant(s)

GROSS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the phone interview on July 7, 2004.
2. ☒ The allowed claim(s) is/are 1,2,13,14,26-30,58-61,64,95,96 and 112-121.
3. ☒ The drawings filed on 15 January 2004 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/413,272.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 4/2/04 and 5/12/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Henry on July 7, 2004.

The application has been amended as follows:

1. (amended) A device for treatment of urinary stress incontinence, comprising:

at least one electrode which is adapted to be implanted in a pelvic muscle of a patient; and

a control unit, which receives signals indicative of abdominal ~~stress~~ pressure or strain in the patient and further comprises a processor which analyzes the signals and determines when an involuntary urine flow is likely, and responsive thereto when the analyzed signals exceed a predetermined threshold indicative of abdominal pressure or strain, applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to stress.

4. (cancelled)

26. (amended) A device according to claim 1, wherein the at least one electrode and the control unit are adapted to be implanted in the body of the patient, and wherein the control unit comprises a rechargeable power source.

58. (amended) A method for treatment of urinary stress incontinence of a patient, comprising:

implanting an electrode in a pelvic muscle of the patient;

receiving a signal from the patient's body indicative of abdominal ~~stress~~ pressure
or strain;

analyzing the received signal using a processor; and

responsive to the analyzed signal, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

95. (amended) A device for inhibiting involuntary urine flow, comprising:

at least one electrode, which is adapted to be implanted in a pelvic muscle of a patient;

a sensor, which ~~is adapted to~~ senses a change in pressure of an abdomen or a urinary bladder of the patient and ~~to~~ generates a signal responsive thereto; and

a control unit, which ~~is adapted to~~ receives the signal, analyzes the signal to determine a level of abdominal stress of the patient, and, responsive thereto, ~~apply~~ applies an electrical waveform to the electrode which stimulates the muscle to contract ~~so as to~~ and inhibit involuntary urine flow through the patient's urethra due to stress,

wherein the control unit comprises a processor which ~~is adapted to~~ analyzes the signals ~~so as to~~ and determines when an involuntary urine flow is likely, whereupon the waveform is applied, and

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wherein the processor is programmable to vary one or more parameters associated with the application of the waveform.

2. The following is an examiner's statement of reasons for allowance: After reviewing the proposed amendment to the claims, the claims were found to be allowable since no prior art could be found teaching or suggesting a device or method of treating or inhibiting involuntary urine flow, comprising: a control unit that receives signals indicative of abdominal pressure or strain in the patient and further comprises a processor which analyzes the signals and determines when an involuntary urine flow is likely and when the analyzed signals exceed a predetermined threshold indicative of abdominal pressure or strain, applies an electrical waveform to the electrode which stimulates the muscle to contract to inhibit involuntary urine flow, as claimed in Claim 1; responsive to a signal indicating abdominal pressure or strain, analyzing the received signal using a processor and then applying an electrical waveform to the electrode to stimulate the muscle to contract to inhibit involuntary urine flow, as claimed in Claim 58; and responsive to a signal indicating the level of abdominal or urinary bladder pressure, the control unit applies an electrical waveform to the electrode which stimulates the muscle to contract to inhibit involuntary urine flow, as claimed in Claim 95. Claims 112-121 remain allowable per the reasons set forth in the paper mailed on July 10, 2003.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Barreras (5,807,397) discloses an implanted stimulator with an inductively rechargeable power source, but fails to disclose the measurement of abdominal pressure or strain and using the measured signal to activate the stimulator to stimulate the muscle to contract to inhibit involuntary urine flow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'BS'.

BS



MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER